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PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 05 January 2001 (05.01.01)	
International application No. PCT/IB00/00310	Applicant's or agent's file reference 088/01360
International filing date (day/month/year) 20 March 2000 (20.03.00)	Priority date (day/month/year) 19 March 1999 (19.03.99)
Applicant LOSHAKOVE, Amir et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
 19 October 2000 (19.10.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Olivia TEFY Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

PCT

NOTIFICATION CONCERNING
AMENDMENTS OF THE CLAIMS(PCT Rule 62 and
Administrative Instructions, Section 417)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as International Preliminary Examining Authority

Date of mailing (day/month/year)

05 January 2001 (05.01.01)

International application No.

PCT/IB00/00310

International filing date (day/month/year)

20 March 2000 (20.03.00)

Applicant

BY-PASS, INC. et al

The International Bureau hereby informs the International Preliminary Examining Authority that no amendments under Article 19 have been received by the International Bureau (Administrative Instructions, Section 417).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

Olivia TEFY

Telephone No. (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

FENSTER, Paul
Fenster & Company Patent
Attorneys, Ltd.
P.O. Box 10256
49002 Petach Tikva
ISRAËL

Date of mailing (day/month/year) 20 September 2001 (20.09.01)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 088/01360	
International application No. PCT/IB00/00310	International filing date (day/month/year) 20 March 2000 (20.03.00)

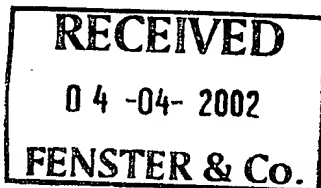
1. The following indications appeared on record concerning: <input checked="" type="checkbox"/> the applicant <input checked="" type="checkbox"/> the inventor <input type="checkbox"/> the agent <input type="checkbox"/> the common representative		
Name and Address LOSHAKOVE, Amir P.O. Box 204 42860 Moshav-Burgeta Israel	State of Nationality IL	State of Residence IL
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning: <input type="checkbox"/> the person <input type="checkbox"/> the name <input checked="" type="checkbox"/> the address <input type="checkbox"/> the nationality <input type="checkbox"/> the residence		
Name and Address LOSHAKOVE, Amir P.O. Box 378 60944 Moshav-Bazra Israel	State of Nationality IL	State of Residence IL
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	
3. Further observations, if necessary:		
4. A copy of this notification has been sent to: <input checked="" type="checkbox"/> the receiving Office <input type="checkbox"/> the designated Offices concerned <input type="checkbox"/> the International Searching Authority <input checked="" type="checkbox"/> the elected Offices concerned <input checked="" type="checkbox"/> the International Preliminary Examining Authority <input type="checkbox"/> other:		

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Elisabeth KÖNIG Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: FENSTER, PAUL
FENSTER & COMPANY PATENT ATTORNEYS,
LTD.
PO BOX 10256
49002 PETACH TIKVA
ISRAEL



PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 088/02281	Date of Mailing (day/month/year) 11 MAR 2002 FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/IL01/00600	International filing date (day/month/year) 28 JUNE 2001
Applicant BY-PASS, INC.	

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 *bis* 1 and 90 *bis* 3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer WILLIAM W. LEWIS <i>Diane Smith</i> Telephone No. (703) 308-0060
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 088/02281	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/IL01/00600	International filing date (<i>day/month/year</i>) 28 JUNE 2001	(Earliest) Priority Date (<i>day/month/year</i>) 11 DECEMBER 2000
Applicant BY-PASS, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 29.1(b)).
- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the
- ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (See Box II).

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☐ the text is approved as submitted by the applicant.
- ☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 2A

- ☒ as suggested by the applicant.
- ☐ because the applicant failed to suggest a figure.
- ☐ because this figure better characterizes the invention.
- ☐ None of the figures.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

The technical features mentioned in the abstract do not include a reference sign between parentheses (PCT Rule 8.1(d)).

Abstract of the Disclosure

Hole forming apparatus (100) for forming an opening in a blood vessel (106) comprising a penetration head (104) for insertion through a wall of a blood vessel (106). The apparatus (100) has a base section (102) and at least one cutting surface (114) on at least one of the base section (102) or the penetration head (104). The cutting surface (114) is adapted to contact first an intima surface of the blood vessel (106). The apparatus (100) further has a shaft operatively connected to the cutting surface (114) and configured to rotate the cutting surface (114) relative to the blood vessel (106), while the penetration head (104) and the base section (102) are brought together, to effect a removal of a plug tissue section from the blood vessel (106).

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL01/00600**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) : A61B 17/32

US CL : 606/185

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/1, 108, 159, 181-185

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
noneElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
none**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,827,316 A (YOUNG et al.) 27 October 1998, see entire document.	1-50
Y	US 5,910,153 A (MAYENBERGER) 08 June 1999, see entire document.	1-50
Y	US 6,022,367 A (SHERTS) 08 February 2000, see entire document.	1-50

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed		"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family
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Date of the actual completion of the international search 30 DECEMBER 2001	Date of mailing of the international search report 11 MAR 2002
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer WILLIAM W. LEWIS <i>Diane Smith</i> Telephone No. (703) 308-0060

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL01/00267

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/08

US CL : 606/153

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/153-155, 99, 104, 108, 184-186; 600/567

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST BRS

search terms: sheath, slot, spike, punch, guidewire, serrated

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---- Y	US 4,696,308 A (MELLER et al.) 29 September 1987, see entire document.	20,24-29, 34-37,43 ----- 21-23, 30-33
X	US 5,201,901 A (HARADA et al.) 13 April 1993, see entire document.	44,46
A	US 5,234,447 A (KASTER et al.), 10 August 1993, see entire document.	53-61
A,P	US 6,193,734 B1 (BOLDUC et al.) 27 February 2001, see entire document.	1-19
A	US 5,823,971 A (ROBINSON et al.) 20 October 1998, fig. 2.	62-63



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Z" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

26 SEPTEMBER 2001

Date of mailing of the international search report

31 DEC 2001

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

JULIAN W. WOO

Telephone No. (703) 308-0421

RECEIVED

1-0-04-2002

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL01/00267

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL01/00267

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s) 1-19 and 51-63, drawn to an anastomosis connector delivery system and a method of mounting an anastomosis connector.

Group II, claim(s) 20-43, drawn to a punch.

Group III, claim(s) 44-52, drawn to a catheter system.

The inventions listed as Groups I-III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I is directed to an anastomotic connector delivery system and method, while Group II is directed to a punch. Group III is directed to a catheter system.

PCT

14
RECD 13 SEP 2001

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 088/01360	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IB00/00310	International filing date (day/month/year) 20 March 2000 (20.03.2000)	Priority date (day/month/year) 19 March 1999 (19.03.1999)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 17/08 and US Cl.: 606/13,221		
Applicant BY-PASS, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

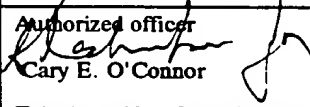
2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 19 October 2000 (19.10.2000)	Date of completion of this report 03 August 2001 (03.08.2001)
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer  Cary E. O'Connor Telephone No. 703-308-0858

I. Basis of the report**1. With regard to the elements of the international application:***

- ☐ the international application as originally filed.
- ☒ the description:
pages 1-21 _____ as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☒ the claims:
pages 22-26 _____, as originally filed
pages NONE _____, as amended (together with any statement) under Article 19
pages 27-29 _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☒ the drawings:
pages 1-25 _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language English which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 62 and 73

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 62 and 73

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>1-58,63-72</u>	YES
	Claims <u>59-61</u>	NO
Inventive Step (IS)	Claims <u>1-58,63-72</u>	YES
	Claims <u>59-61</u>	NO
Industrial Applicability (IA)	Claims <u>1-61,63-72</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

-----NEW CITATIONS-----

US 3,908,662 A (RAZGULOV ET AL) 30 SEPTEMBER 1975, see entire document.

Claims 1-58 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest an anastomosis connector comprising a plurality of ring segments forming a ring shape, a pivot bar connected to one of the segments and a spike mounted on the pivot bar wherein radial deformation of the ring shape does not effect the spike rotation position.

Claims 59-61 lack novelty under PCT Article 33(2) as being anticipated by Razgulov et al (3,908,662). Razgulov teaches a method of everting a blood vessel comprising engaging a tip of the vessel at a plurality of points around its circumference, inverting the tip by inverting the points and pulling the points towards the distal end of the vessel (see figs 13-15).

Claim 63 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest apparatus for graft eversion comprising a plurality of forceps each having a joint for rotating the forceps.

Claims 64 and 65 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of measuring a graft size comprising mounting the graft on two extensions, one coupled to a spring with a scale and one coupled to a handle, separating the extensions and reading the measurement on the scale.

Claims 66 and 67 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a hole punch having a tip and a shaft having a depression with a diameter that increases away from the tip, and an outer tube mounted on the shaft and having an inner diameter that is in the range of the increasing diameter of the depression.

Claims 68-70 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of forming an oblique anastomosis connector comprising providing a non-oblique connector, deforming the connector to the desired degree of oblique-ness and heat treating the connector.

Claims 71 and 72 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a side mounted delivery system comprising a handle with an opening in its side, a graft delivery tool, and a groove and projection mechanism interconnecting the tool and the handle.

088/01360 a01

PCT/IB 00/00310
REAVIS 19 OCT 2000

55. A connector according to claim 45, wherein all of said plurality of elements have a constant width.

56. A connector according to claim 45, comprising a strain dissipation element at a point of connection of at least one of said elements and a spike element to which said ring segment is attached.

57. A connector according to claim 56, wherein said strain dissipation element comprises a thickening of said axially spaced element.

10

58. A connector according to claim 57, wherein said thickening defines an aperture.

59. A method of everting a blood vessel, comprising:
engaging a tip of said vessel at a plurality of points around its circumference;
15 inverting said tip by inverting said points; and
pulling said inverted points towards a distal end of said blood vessel.

60. A method according to claim 59, wherein said plurality comprises at least four points.

20 61. A method according to claim 59, wherein said engaging comprises engaging using forceps and wherein said inverting comprises rotating said forceps.

62. A method according to any of claims 59-61, wherein said pulling comprises pulling different ones of said points different amounts.

25

63. Apparatus for graft eversion of a graft over a shaft having a tip, comprising:
a handle for engaging said shaft;
a plurality of forceps arranged to engage a tip of said graft where it protrudes from said shaft; and

30 a plurality of joints, each one associated with one of said forceps, for rotating said forceps pulling a tip of each of said forceps axially along said shaft.

64. A method of measuring a graft size, comprising:

PCRB 00/00310

PEA/US 19 OCT 2000

088/01360 a01

mounting a tip of said graft on two extensions, one extension coupled to a spring and
one extension coupled to a handle;

manipulating said handle such that said extensions separate;

reading a measurement on a scale coupled to said spring; and

5 selecting an anastomosis connector responsive to said read measurement.

65. A method according to claim 64, comprising further manipulating said handle to
stretch said graft tip.

10 66. A hole puncher, comprising:

a sharp tip for forming a puncture in a blood vessel;

a shaft having a varying diameter and having a depression formed therein for engaging
a wall of said blood vessel, said diameter substantially matching a diameter of said tip at one
end of the shaft, said diameter increasing away from said tip for a first distance and said
15 diameter then defining a slope of diminishing diameter towards said depression; and

an outer tube mounted on said shaft and having an end, said outer tube having an inner
diameter of said end that is in a range of diameters defined by said slope of diminishing
diameters.

20 67. A puncher according to claim 66, wherein said end of said outer tube has a smaller
outer diameter than a more proximal portion of said outer tube.

68. A puncher according to claim 66 or claim 67, wherein said diminishing diameter slope
is obliquely arranged around said shaft.

25

69. A method of forming an oblique anastomosis connector, comprising:

providing a non-oblique anastomosis connector;

mounting said connector in a restraint;

manipulating said restraints to deform said connector to a desired degree of
30 obliqueness; and

heat-treating said connector after said manipulation, to maintain said distortion.

70. A method according to claim 69, comprising heat-treating said connector prior to said
mounting, to train a deformation of a spike portion of said connector.

088/01360 a01

T/B 00/00310
PEAVUS 19 OCT 2000

71. A side mounted delivery system, comprising:
a handle including an opening in its side;
a graft delivery tool adapted to fit through said opening; and
5 a groove and projection mechanism slidably interconnecting said tool and said handle.
72. A system according to claim 71, comprising a snap-lock mechanism for axially fixing
said handle relative to said tool.
- 10 73. A method according to any of claims 59-61, wherein said points are inverted
simultaneously.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: MAIER FENSTER
FENSTER & COMPANY PATENT
ATTORNEYS, LTD.
POST OFFICE BOX 10256
48002 DETROIT, MI 48202-0256

RECEIVED
26-12-2000
FENSTER & Co.

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 088/01360	Date of Mailing (day/month/year) 05 SEP 2000
International application No. PCT/IB00/00310	International filing date (day/month/year) 20 MARCH 2000
Applicant BY-PASS, INC.	

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
 - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 bis 1 and 90 bis 3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer <i>[Signature]</i> JONATHAN GOLDBERG
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0161

TENT COOPERATION TREA'

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 088/01360	<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> FOR FURTHER ACTION </div> <div style="width: 50%;"> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. </div> </div>	
International application No. PCT/IB00/00310	International filing date (day/month/year) 20 MARCH 2000	(Earliest) Priority Date (day/month/year) 19 MARCH 1999
Applicant BY-PASS, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☐ Unity of invention is lacking (See Box II).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No. 1

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ None of the figures.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

NEW ABSTRACT

An anastomosis connector comprises a plurality of ring segments (106), together defining a radially expandable ring-like shape (106) having a lumen, at least one pivot bar (114) coupled to at least one of said ring segments (106), at least one spike (109) mounted on said pivot bar (114), and rotatable around said pivot bar (114), wherein radial deformation of said ring-like shape (106) does not substantially directly affect the said spike (109) rotational position.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB00/00310

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/08

US CL : 606/153, 221

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/153, 221

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

BRS

Search Terms: anastomosis, \$lock\$ or mating, teeth or ratchet\$2, ring, strut

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,214,586 A (MERILE) 29 July 1980, whole document.	1-65
Y	US 4,657,019 A (WALSH et al.) 14 April 1987, whole document.	1-65
Y	US 5,234,448 A (WHOLEY et al.) 10 August 1993, whole document.	1-65
Y	US 5,234,447 A (KASTER et al.) 10 August 1993, whole document.	65-72
Y	US 5,695,504 A (GIFFORD, III et al.) 09 December 1997, whole document.	65-72
A	US 4,366,819 A (KASTER) 04 January 1983.	1-65

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"A" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

07 AUGUST 2000

Date of mailing of the international search report

05 SEP 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

JONATHAN GOLDBERG

Telephone No. (703) 308-0161

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB00/00310

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3,908,662 A (RAZGULOV et al.) 30 September 1975.	1-65

PATENT COOPERATION TREATY

RECEIVED

05-09-2001

FENSTER & Co.

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITYTo:
MAIER FENSTER
FENSTER & COMPANY PATENT ATTORNEYS, LTD.
P.O. BOX 10256
PETACH TIKVA, ISRAEL

PTO/PCT Rec'd 17 SEP 2001

PCT

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing
(day/month/year)

30 AUG 2001

Applicant's or agent's file reference

088/01360

IMPORTANT NOTIFICATION

International application No.

PCT/IB00/00310

International filing date (day/month/year)

20 March 2000 (20.03.2000)

Priority date (day/month/year)

19 March 1999 (19.03.1999)

Applicant

BY-PASS, INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume I) of the PCT Applicant's Guide.

BEST AVAILABLE COPY

Name and mailing address of the IPEA/US

Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703)305-3230

Form PCT/IPEA/416 (July 1992)

Authorized officer

Cary E. O'Connor

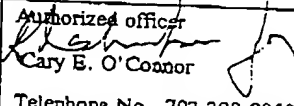
Telephone No. 703-308-0858

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 088/01360		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IB00/00310	International filing date (day/month/year) 20 March 2000 (20.03.2000)	Priority date (day/month/year) 19 March 1999 (19.03.1999)	
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 17/08 and US Cl.: 606/13,221			
Applicant BY-PASS, INC.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>3</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none">I <input checked="" type="checkbox"/> Basis of the reportII <input type="checkbox"/> PriorityIII <input checked="" type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicabilityIV <input type="checkbox"/> Lack of unity of inventionV <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statementVI <input type="checkbox"/> Certain documents citedVII <input type="checkbox"/> Certain defects in the international applicationVIII <input type="checkbox"/> Certain observations on the international application			
Date of submission of the demand 19 October 2000 (19.10.2000)		Date of completion of this report 03 August 2001 (03.08.2001)	
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230		Authorized officer  Cary E. O'Connor Telephone No. 703-308-0858	

Form PCT/IPEA/409 (cover sheet)(July 1998)

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed.☒ the description:

pages 1-21 as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

☒ the claims:

pages 22-26 as originally filed

pages NONE, as amended (together with any statement) under Article 19

pages 27-29, filed with the demand

pages NONE, filed with the letter of _____

☒ the drawings:

pages 1-25 as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

☐ the sequence listing part of the description:

pages NONE as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language English which is:☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 43.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. ☐ The amendments have resulted in the cancellation of:☐ the description, pages NONE☐ the claims, Nos. NONE☐ the drawings, sheets/fig NONE5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IB00/00310

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 62 and 73

because:

- ☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination (*specify*):

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 62 and 73

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)

Claims 1-58,63-72 YES
Claims 59-61 NO

Inventive Step (IS)

Claims 1-58,63-72 YES
Claims 59-61 NO

Industrial Applicability (IA)

Claims 1-61,63-72 YES
Claims NONE NO

2. CITATIONS AND EXPLANATIONS

NEW CITATIONS

US 3,908,662 A (RAZGULOV ET AL) 30 SEPTEMBER 1975, see entire document.

Claims 1-58 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest an anastomosis connector comprising a plurality of ring segments forming a ring shape, a pivot bar connected to one of the segments and a spike mounted on the pivot bar wherein radial deformation of the ring shape does not effect the spike rotation position.

Claims 59-61 lack novelty under PCT Article 33(2) as being anticipated by Razgulov et al (3,908,662). Razgulov teaches a method of everting a blood vessel comprising engaging a tip of the vessel at a plurality of points around its circumference, inverting the tip by inverting the points and pulling the points towards the distal end of the vessel (see figs 13-15).

Claim 63 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest apparatus for graft conversion comprising a plurality of forceps each having a joint for rotating the forceps.

Claims 64 and 65 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of measuring a graft size comprising mounting the graft on two extensions, one coupled to a spring with a scale and one coupled to a handle, separating the extensions and reading the measurement on the scale.

Claims 66 and 67 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a hole punch having a tip and a shaft having a depression with a diameter that increases away from the tip, and an outer tube mounted on the shaft and having an inner diameter that is in the range of the increasing diameter of the depression.

Claims 68-70 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of forming an oblique anastomosis connector comprising providing a non-oblique connector, deforming the connector to the desired degree of oblique-ness and heat treating the connector.

Claims 71 and 72 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a side mounted delivery system comprising a handle with an opening in its side, a graft delivery tool, and a groove and projection mechanism interconnecting the tool and the handle.

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 :

A61B 17/08

AI

(11) International Publication Number:

WO 00/56228

(43) International Publication Date: 28 September 2000 (28.09.00)

(21) International Application Number: PCT/IL00/00310

(22) International Filing Date: 20 March 2000 (20.03.00)

(30) Priority Data:

129067	19 March 1999 (19.03.99)	IL
PCT/IL99/00284	30 May 1999 (30.05.99)	IL
PCT/IL99/00285	30 May 1999 (30.05.99)	IL
PCT/IL99/00670	8 December 1999 (08.12.99)	IL
PCT/IL99/00674	9 December 1999 (09.12.99)	IL

(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application

US PCT/IL99/00674 (CIP)
Filed on 9 December 1999 (09.12.99)

(71) Applicant (for all designated States except US): BY-PASS, INC. [US/US]; 40 Ramland Road, Orangeburg, NY 10962 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): LOSHAKOVE, Amir [IL/IL]; P.O. Box 204, 42860 Moshav Burgeta (IL). KILEMNIK, Ido [IL/IL]; Nordau Street 35, 46585 Herzlia (IL). KEREN, Dvir [IL/IL]; Harav Kook Street 31, 49315

Petach Tikva (IL). ZIMET, Nachman [IL/IL]; Hazor Street 5, 69016 Tel Aviv (IL).

(74) Agents: FENSTER, Paul et al.; Fenster & Company Patent Attorneys, Ltd., P.O. Box 10256, 49002 Petach Tikva (IL).

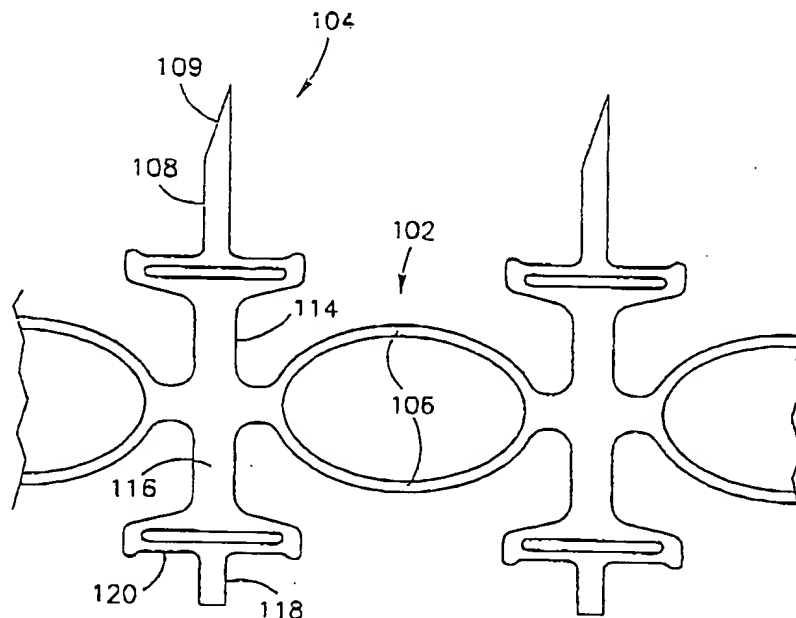
(81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: LOW PROFILE ANASTOMOSIS CONNECTOR



(57) Abstract

An anastomosis connector comprises a plurality of ring segments (106), together defining a radially expandable ring-like shape (106) having a lumen; at least one pivot bar (114) coupled to at least one of said ring segments (106); at least one spike (109) mounted on said pivot bar (114) and rotatable around said pivot bar (114), wherein radial deformation of said ring-like shape (106) does not substantially

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

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PCT

From the INTERNATIONAL BUREAU

NOTICE INFORMING THE APPLICANT OF THE
COMMUNICATION OF THE INTERNATIONAL
APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:

FENSTER, Paul
Fenster & Company Patent
Attorneys, Ltd.
P.O. Box 10256
49002 Petach Tikva
ISRAEL

Date of mailing (day/month/year)

28 September 2000 (28.09.00)

Applicant's or agent's file reference

088/01360

IMPORTANT NOTICE

International application No.

PCT/IB00/00310

International filing date (day/month/year)

20 March 2000 (20.03.00)

Priority date (day/month/year)

19 March 1999 (19.03.99)

Applicant

BY-PASS, INC. et al

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:

AG, AU, DZ, KP, KR, US.



In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

AE, AL, AM, AP, AT, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EA, EE, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, OA, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW

The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application. (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 28 September 2000 (28.09.00) under No. WO 00/56228.

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer:

J. Zahra

Facsimile No. (41-22) 740.14.35

Telephone No. (41-22) 338.83.38

Continuation of Form PCT/IB/308

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF
THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

Date of mailing (day/month/year) 28 September 2000 (28.09.00)	IMPORTANT NOTICE
Applicant's or agent's file reference 088/01360	International application No. PCT/IB00/00310

The applicant is hereby notified that at the time of establishment of this Notice, the time limit under Rule 46.1 for making amendments under Article 19 has not yet expired and the International Bureau had received neither such amendments nor a declaration that the applicant does not wish to make amendments.

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ATTORNEY

SEP 17 2001

55. A connector according to claim 45, wherein all of said plurality of elements have a constant width.

56. A connector according to claim 45, comprising a strain dissipation element at a point of connection of at least one of said elements and a spike element to which said ring segment is attached.

57. A connector according to claim 56, wherein said strain dissipation element comprises a thickening of said axially spaced element.

58. A connector according to claim 57, wherein said thickening defines an aperture.

59. A method of everting a blood vessel, comprising:
engaging a tip of said vessel at a plurality of points around its circumference;
inverting said tip by inverting said points; and
pulling said inverted points towards a distal end of said blood vessel.

60. A method according to claim 59, wherein said plurality comprises four points.

61. A method according to claim 59, wherein said engaging comprises engaging using forceps and wherein said inverting comprises rotating said forceps.

62. A method according to any of claims 59-61, wherein said pulling comprises pulling different ones of said points different amounts.

63. Apparatus for graft eversion of a graft over a shaft having a tip, comprising:
a handle for engaging said shaft;
a plurality of forceps arranged to engage a tip of said graft where it protrudes from said shaft; and

a plurality of joints, each one associated with one of said forceps, for rotating said forceps pulling a tip of each of said forceps axially along said shaft.

64. A method of measuring a graft size, comprising:

mounting a tip of said graft on two extensions, one extension coupled to a spring and one extension coupled to a handle;

manipulating said handle such that said extensions separate;

reading a measurement on a scale coupled to said spring; and

5 selecting an anastomosis connector responsive to said read measurement.

65. A method according to claim 64, comprising further manipulating said handle to stretch said graft tip.

10 66. A hole puncher, comprising:

a sharp tip for forming a puncture in a blood vessel;

a shaft having a varying diameter and having a depression formed therein for engaging a wall of said blood vessel, said diameter substantially matching a diameter of said tip at one end of the shaft, said diameter increasing away from said tip for a first distance and said
15 diameter then defining a slope of diminishing diameter towards said depression; and

an outer tube mounted on said shaft and having a tip, said outer tube having an inner diameter of said tip that is in a range of diameters defined by said slope of diminishing diameters.

20 67. A puncher according to claim 66, wherein said tip of said outer tube has a smaller outer diameter than a more proximal portion of said outer tube.

68 A puncher according to claim 66 or claim 67, wherein said diminishing diameter slope is obliquely arranged around said shaft.

25

69. A method of forming an oblique anastomosis connector, comprising:

providing a non-oblique anastomosis connector;

mounting said connector in a restraint;

manipulating said restraints to deform said connector to a desired degree of
30 obliqueness; and

heat-treating said connector after said manipulation, to maintain said distortion.

70. A method according to claim 69, comprising heat-treating said connector prior to said mounting, to train a deformation of a spike portion of said connector.

71. A side mounted delivery system, comprising:
a handle including an opening in its side;
a graft delivery tool adapted to fit through said opening; and
5 a groove and projection mechanism slidably interconnecting said tool and said handle.
72. A system according to claim 71, comprising a snap-lock mechanism for axially fixing
said handle relative to said tool.

INTERNATIONAL SEARCH REPORT

Intern	applicati n No.
PCT	0310

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 17/08

US CL :606/153, 221

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/153, 221

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

BRS

Search Terms: anastomosis, \$lock\$ or mating, teeth or ratchet\$2, ring, strut

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,214,586 A (MERILE) 29 July 1980, whole document.	1-65
Y	US 4,657,019 A (WALSH et al.) 14 April 1987, whole document.	1-65
Y	US 5,234,448 A (WHOLEY et al.) 10 August 1993, whole document.	1-65
Y	US 5,234,447 A (KASTER et al.) 10 August 1993, whole document.	65-72
Y	US 5,695,504 A (GIFFORD, III et al.) 09 December 1997, whole document.	65-72
A	US 4,366,819 A (KASTER) 04 January 1983.	1-65

☒ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

07 AUGUST 2000

Date of mailing of the international search report

05 SEP 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

JONATHAN GOLDBERG

Telephone No. (703) 308-0161

INTERNATIONAL SEARCH REPORT

International application No.
PCT/00/00310

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3,908,662 A (RAZGULOV et al.) 30 September 1975.	1-65

1/25

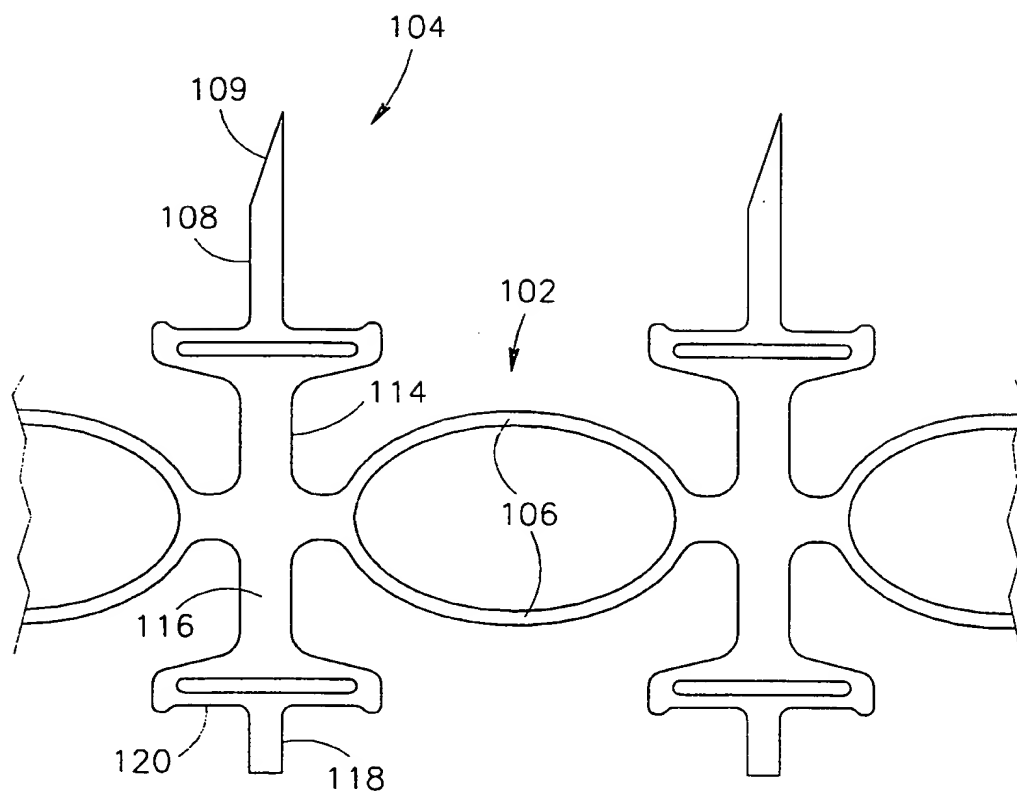


FIG.1

2/25

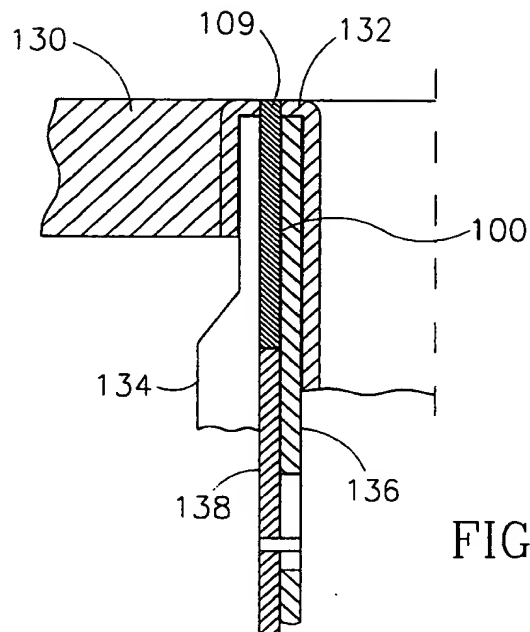


FIG. 2A

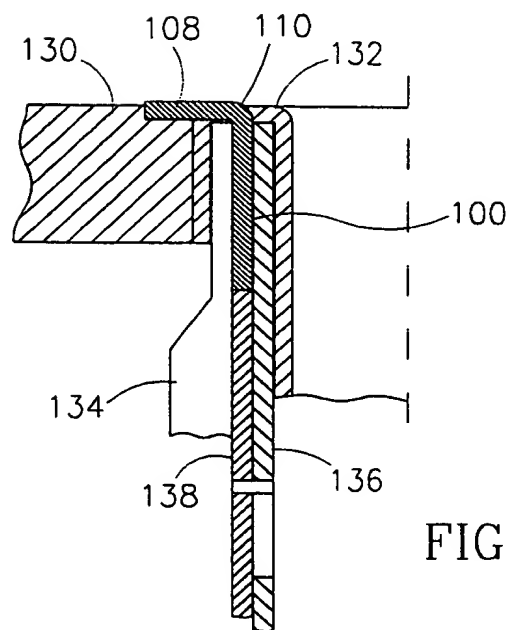


FIG. 2B

3/25

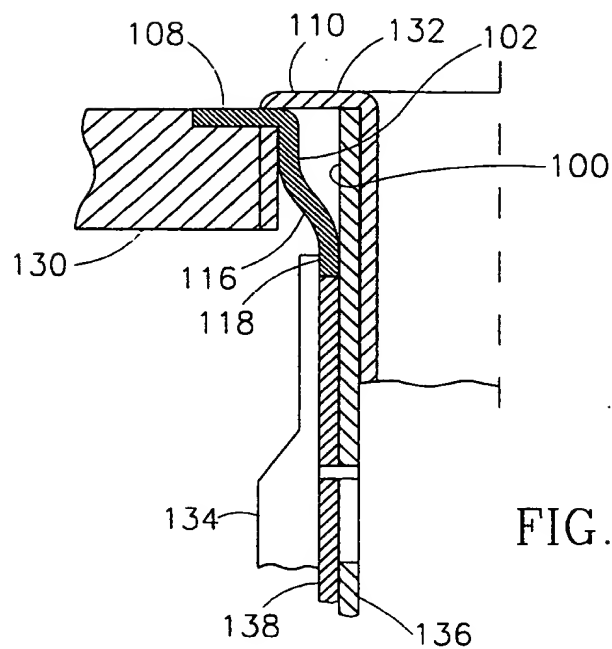


FIG. 2C

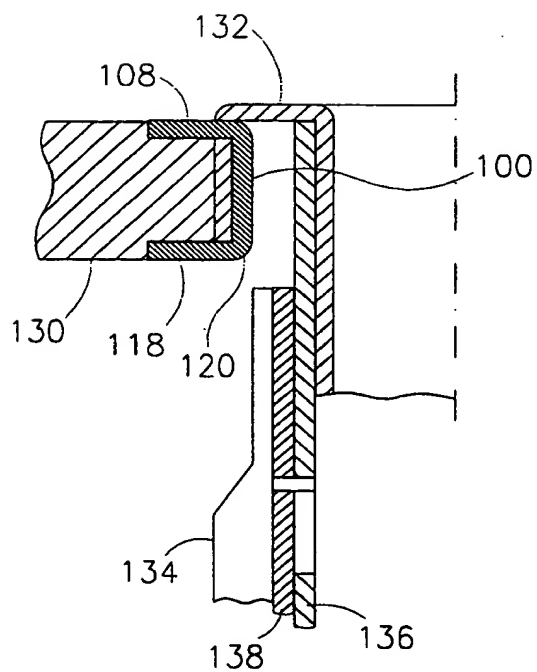


FIG. 2D

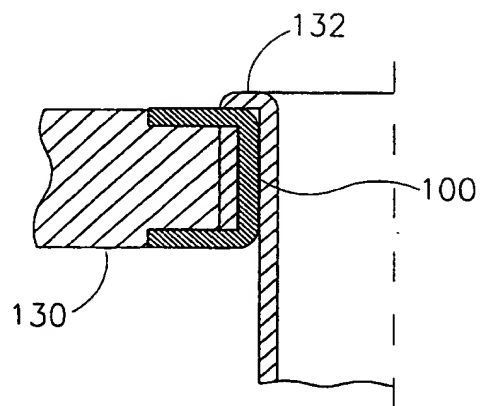


FIG. 2E

088/01360

Application No. PCT/IB00/00310

Applicant: By-pass Inc. et al.

Filed: March 20, 2000

Title: Low Profile Anastomosis Connector

Examiner: Cary E. O'Connor

COPY**RESPONSE TO WRITTEN OPINION**

This letter is in response to a written opinion dated February 22, 2001. Claims 59-61 of application No. PCT/IB00/00310; "Low Profile Anastomosis Connector" stand rejected under PCT Article 33(2) as being anticipated by RAZGULOV et al. (3,908,662).

In the invention as claimed in claim 59, the points are inverted after being engaged by the blood vessel.

For example, in Fig. 1, points 109 and 118 are on the same axial plane as component 102. In Fig. 2A point 109 is unbent as it comes in contact with blood vessel 132. Further, the invention as claimed in claim 59 *requires* that the tip be inverted *by* inverting the points.

In contrast US 3,908,622, Figs. 13-15 demonstrate a plurality of points that are *already* inverted when they engage the blood vessel. As seen in Fig. 15, the inverted points are not inverted further during the loading of the blood vessel.

The following corrections of typographic errors and omissions of numbering in Figs. 1, 2A-E have been made according to representations in the application text.

In Fig. 1, number 110 has been added, pointing to the upper pivot bar.

In Fig. 2A, number 110 has been added, pointing to the upper pivot bar,
number 120 has been added, pointing to the lower pivot bar and
number 118 has been added, pointing to the lower spike.

In Fig. 2B, number 120 has been added, pointing to the lower pivot bar and
number 118 has been added, pointing to the lower spike.

In Fig. 2C number 110 has been corrected to point to the upper pivot bar
number 100 has been corrected to point to the connector and
number 120 has been added, pointing to the lower pivot bar.

In Fig. 2D, number 110 has been added, pointing to the upper pivot bar.

In Fig. 2E, number 110 has been added, pointing to the upper pivot bar,
number 120 has been added, pointing to the lower pivot bar,
number 108 has been added, pointing to the upper spike and
number 118 has been added, pointing to the lower spike.

Claims 62 and 73 stand objected to for improper multiple dependent claims under PCT rule 6.4(a).

PCT rule 6.4(a) indeed states, "Multiple dependent claims shall not serve as a basis for any other multiple dependent claim." Both claims 62 and 73 are dependent on claims 59-61 which are either independent (claim 59), or singly dependent on claim 59 (claims 60 and 61). Thus claims 62 and 73 are in proper form.

In view of the above remarks and amendments, a positive IPER is respectfully awaited.

A copy of this response is being forwarded to you by courier.

Respectfully Submitted,



Paul Fenster

Agent for the Applicant

PATENT COOPERATION TREATY

FILE COPY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
MAIER FENSTER
FENSTER & COMPANY PATENT ATTORNEYS, LTD.
P.O. BOX 10256
PETACH TIKVA, ILX 49002

PCT

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference 088/01360		Date of Mailing (day/month/year) REPLY DUE within 2 months/days from the above date of mailing
International application No. PCT/IB00/00310	International filing date (day/month/year) 20 March 2000 (20.03.2000)	Priority date (day/month/year) 19 March 1999 (19.03.1999)
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61B 17/08 and US Cl.: 606/13,221		
Applicant BY-PASS, INC.		

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application
3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 19 July 2001 (19.07.2001).

Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Cary E. O'Connor Telephone No. 703-308-0858
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WRITTEN OPINION

International application No.

PCT/IB00/00310

FILE COPY

I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
 pages 1-21, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____
- ☒ the claims:
 pages 22-26, as originally filed
 pages NONE, as amended (together with any statement) under Article 19
 pages 27-29, filed with the demand
 pages NONE, filed with the letter of _____
- ☒ the drawings:
 pages 1-25, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages NONE, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language English which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NOE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

WRITTEN OPINION

International application No.

PCT/IB00/00310

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 62 and 73

because:

- ☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 62 and 73 are so unclear that no meaningful opinion could be formed (*specify*):

Claims 62 and 73 are improper multiple dependent claims under PCT rule 6.4(a).

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

- ☐ no international search report has been established for said claims Nos. _____.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
☐ the computer readable form has not been furnished or does not comply with the standard.

WRITTEN OPINION

International application No.
PCT/IB00/00310

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>1-58, 63-72</u>	YES
	Claims <u>59-61</u>	NO
Inventive Step (IS)	Claims <u>1-61, 63-72</u>	YES
	Claims <u>NONE</u>	NO
Industrial Applicability (IA)	Claims <u>NONE</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-58 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest an anastomosis connector comprising a plurality of ring segments forming a ring shape, a pivot bar connected to one of the segments and a spike mounted on the pivot bar wherein radial deformation of the ring shape does not effect the spike rotation position.

Claims 59-61 lack novelty under PCT Article 33(2) as being anticipated by Razgulov et al (3,908,662). Razgulov teaches a method of everting a blood vessel comprising engaging a tip of the vessel at a plurality of points around its circumference, inverting the tip by inverting the points and pulling the points towards the distal end of the vessel (see figs 13-15).

Claim 63 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest apparatus for graft eversion comprising a plurality of forceps each having a joint for rotating the forceps.

Claims 64 and 65 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of measuring a graft size comprising mounting the graft on two extensions, one coupled to a spring with a scale and one coupled to a handle, separating the extensions and reading the measurement on the scale.

Claims 66 and 67 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a hole punch having a tip and a shaft having a depression with a diameter that increases away from the tip, and an outer tube mounted on the shaft and having an inner diameter that is in the range of the increasing diameter of the depression.

Claims 68 and 69 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of forming an oblique anastomosis connector comprising providing a non-oblique connector, deforming the connector to the desired degree of oblique-ness and heat treating the connector.

Claims 71 and 72 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a side mounted delivery system comprising a handle with an opening in its side, a graft delivery tool, and a groove and projection mechanism interconnecting the tool and the handle.

----- NEW CITATIONS ----- ~~US~~ 3,908,662 A (RAZGULOV ET AL) 30 SEPTEMBER 1975, see entire document.

=
1-58
63-72

ob
62, 73
✓ 59-61